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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/939,863	08/27/2001	Michael Milbocker	Praxis-3	7242

7590

04/13/2004

PROMETHEAN SURGICAL DYNAMICS LLC
3 GILL ST. #FIG
WOBURN, MA 01801

EXAMINER

PREBILIC, PAUL B

ART UNIT	PAPER NUMBER
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3738

DATE MAILED: 04/13/2004

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/939,863

Applicant(s)

MILBOCKER, MICHAEL

Examiner

Paul B. Prebilic

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 January 2004.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-29 is/are pending in the application.
- 4a) Of the above claim(s) 14-16 and 18-29 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10, 12 and 13 is/are rejected.
- 7) ☒ Claim(s) 11 and 17 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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Election/Restrictions

Claims 14-16 and 18-29 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 3 filed August 22, 2003.

Newly submitted claims 28 and 29 are directed to a non-elected invention. For this reason, these claims are also withdrawn. Even though they depend from claim 1 (an elected claim), their preambles clearly suggest that they belong to a non-elected invention.

Specification

The disclosure is objected to because of the following informalities:

On page 20, line 6, "aq" should be ---a---.

Appropriate correction is required.

Claim Objections

Claim 13 is objected to because of the following informalities:

On line 3 of claim 13, the language is grammatically awkward or lacks clear antecedent basis. The Examiner suggests changing "suturing absorbent pad" to ---suturing at least one absorbent pad--- in order to overcome this objection. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

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The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 13 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. There is no original support for the combination of a prosthesis having an adhesive coating on it sutured to a pad which has had adhesive applied to it. Furthermore, the specification fails to explain how to cover an internal tissue defect and surrounding tissue with an adhesive coated prosthetic and also place at least one absorbent pad on said tissue while suturing it to said prosthetic as claimed. This is due to the fact that the adhesive is only originally taught as being applied to either the prosthetic or the pad, but not both at the same time.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3, 5, and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Sawyer (US 5,156,613). Sawyer anticipates the claim language where the prosthetic as claimed is the collagen filler material (60) of Sawyer; see Figure 3 as well as column 7, line 61 to column 8, line 47, the abstract and column 2, lines 23-51. The prosthetic

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coating as claimed is the fibrin glue or adhesive coated over the filler material; see column 8, lines 22-33.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over Polson et al (US 5,487,897) alone. Polson et al discloses an embodiment with a formed implant that is applied to a wound site with adhesive but lacks the step of applying adhesive to the implant before application to the tissue; see the abstract; column 3, lines 31-54, column 4, lines 43-46; column 16, lines 58 to column 17, line 13 and column 18, lines 33-38. However, at the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to apply adhesive also to the implant because Applicants have not disclosed that applying adhesive to the prosthetic provides some advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicants' invention to perform equally well because the merely adhesive needs to be between the tissue and prosthetic surfaces to function properly. It does not matter whether it is applied to one surface, the other surface, or to both surfaces. Therefore, it would have been an obvious matter of design choice to modify Polson to obtain the invention as specified in the claims.

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Claims 4-6 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Polson et al (US 5,487,897) in view of English et al (US 4,804,691). Polson fails to disclose the specific types of adhesives used therewith as claimed. However, English teaches that fibrin, polyurethane, and polyisocyanate adhesives were known and available to the art at the time the invention was made; see column 1, lines 21-61. Therefore, it would have been prima facie obvious to an ordinary artisan to substitute any of these other known surgical adhesives for the adhesive of Polson for the same reasons that the prior art used the same and to adapt the device to the particular patient's need.

Claims 4, 6, and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sawyer et al (US 5,156,613) in view of English et al (US 4,804,691). Sawyer fails to disclose the types of adhesives as claimed. However, English teaches that fibrin, polyurethane, and polyisocyanate adhesives were known and available to the art at the time the invention was made; see column 1, lines 21-61. Therefore, it would have been prima facie obvious to an ordinary artisan to substitute any of these other known surgical adhesives for the adhesive of Sawyer for the same reasons that the prior art used the same and to adapt the device to the particular patient's need.

Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Polson et al (US 5,487,897) in view of Owen et al (US 6,211,335). Polson fails to disclose the use of albumin solder as claimed. However, Owen teaches that it was known to use albumin solder in similar tissue bonding methods; see column 9, lines 7-14. Hence, it is the Examiner's position that it would have been prima facie obvious to substitute or

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combine the albumin solder of Owen for/with the adhesive of either Polson for the same reasons that Owen uses the same and in order to adapt the Polson device to the particular patient need.

Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Polson et al (US 5,487,897) or Sawyer (US 5,156,613) in view of Ganster et al (US 6,191,216). Polson or Sawyer fails to disclose the use of open cell polyurethane adhesive as claimed. However, Ganster teaches that it was known to use foamed (open cell) polyurethane adhesive in similar tissue bonding methods; see column 1, lines 11-39 and column 6, lines 38-47. Hence, it is the Examiner's position that it would have been prima facie obvious to substitute or combine the foamed adhesive of Ganster for/with the adhesives of either Polson or Sawyer for the same reasons that Ganster uses the same and in order to adapt the Polson or Sawyer devices to the particular patient need.

Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sawyer et al (US 5,156,613) alone. Sawyer meets the claim language as set forth above, but fails to disclose the repair of an inguinal hernia as claimed. However, since Sawyer et al teaches that the method thereof can be used for any internal surgical repair (see previous citations), it would have been prima facie obvious to use the Sawyer device to repair an inguinal hernia so as to help such patients also.

Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sawyer (US 5,156,613) in view of Kreamer (US 4,577,631). Sawyer fails to disclose the use of encapsulated glue as claimed. However, Kreamer teaches that it was known to use encapsulated glue on similar tissue replacement/repair implants; see column 7, lines 3-

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18. Therefore, it is the Examiner's position that it would have been obvious to use encapsulated glue with the Sawyer device for the same reasons as Kreamer and in order to better ensure that the Sawyer implant is located in the correct place before the adhesive is activated.

Allowable Subject Matter

Claims 11 and 17 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

Applicant's arguments with respect to the active claims have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 USC 102 or 35 USC 103(a) once the aforementioned issue(s) is/are addressed.

Applicant is respectfully requested to provide a list of all copending applications that set forth similar subject matter to the present claims. A copy of such copending claims is respectfully requested in response to this Office action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul Prebilic whose telephone number is (703) 308-2905. The examiner can normally be reached on Monday-Thursday from 6:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached on (703) 308-2111. The fax phone number for this Technology Center is (703) 872-9306.

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Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 3700 receptionist whose telephone number is (703) 308-0858.

A handwritten signature in black ink, appearing to read "Paul Prebilic", with a horizontal line extending to the right.

Paul Prebilic
Primary Examiner
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